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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER
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SWARTZ, RODNEY P

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 11/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/777,131

Applicant(s)

GICQUEL, BRIGITTE

Examiner

Rodney P. Swartz, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 16 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 26,28,29,31-43 and 45-52 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 32,35-38,40,41,45 and 48-51 is/are allowed.
- 6) ☒ Claim(s) 26,28,29,31,33,34,39,42,43,46,47 and 52 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. Applicant's Response to Final Office Action, received 16 August 2006, is acknowledged.

Claims 26 and 29 have been amended.

2. Claims 26, 28, 29, 31-43, and 45-52 are pending and under consideration.

### **Rejection Withdrawn**

3. The rejection of claims 26, 28, 29, and 31 under 35 U.S.C. 112, second paragraph, as being indefinite for "comprising an open reading frame of the *Rv3908* gene", is withdrawn in light of the amendment of the claims.

### **Claim Rejections - 35 USC § 112**

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 26 and 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 26 is drawn to a purified polynucleotide comprising SEQ ID NO:30, wherein codon 48 of SEQ ID NO:30 is GGG or a polynucleotide fully complementary thereto. The listing of SEQ ID NO:30 shows that codon 48 is CGG, not GGG. Therefore it is unclear how a purified polynucleotide comprises both SEQ ID NO:30 with CGG at codon 48, but is listed as GGG. The

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examiner suggests that the claim language be amended to recite: "A purified polynucleotide comprising SEQ ID NO:30 except that codon 48 (CGG) of SEQ ID NO:30 has been changed to GGG". (This language is consistent with specification, paragraph 073).

Dependent claim 28 recites "The purified polynucleotide as claimed in claim 26, which comprises SEQ ID NO:3, 4, or both 3 and 4 or the complement of 3, 4, or both 3 and 4." However, claim 26 does not indicate any requirement that it contain either SEQ ID NO:3 or 4. It is suggested that the claim language be amended to recite: "The purified polynucleotide as claimed in claim 26 which further comprises a sequence selected from the group consisting of: SEQ ID NO:3, or SEQ ID NO:4, or both SEQ ID NO:3 and SEQ ID NO:4, or the complement of SEQ ID NO:3, or the complement of SEQ ID NO:4, or the complement of both SEQ ID NO:3 and SEQ ID NO:4"

7. Claims 29 and 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is drawn to a purified polynucleotide comprising SEQ ID NO:29, wherein codon 58 of SEQ ID NO:29 is CGA or a polynucleotide fully complementary thereto. The listing of SEQ ID NO:29 shows that codon 58 is GGA, not CGA. Therefore it is unclear how a purified polynucleotide comprises both SEQ ID NO:29 with GGA at codon 58, but is listed as CGA. The examiner suggests that the claim language be amended to recite: "A purified polynucleotide comprising SEQ ID NO:29 except that codon 58 (GGA) of SEQ ID NO:29 has been changed to CGA". (This language is consistent with specification, paragraph 075).

Dependent claim 31 recites "The purified polynucleotide as claimed in claim 29, which comprises SEQ ID NO:1, 2, or both 1 and 2 or the complement of 1, 2, or both 1 and 2."

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However, claim 29 does not indicate any requirement that it contain either SEQ ID NO:1 or 2.

It is suggested that the claim language be amended to recite: "The purified polynucleotide as claimed in claim 29 which further comprises a sequence selected from the group consisting of: SEQ ID NO:1, or SEQ ID NO:2, or both SEQ ID NO:1 and SEQ ID NO:2, or the complement of SEQ ID NO:1, or the complement of SEQ ID NO:2, or the complement of both SEQ ID NO:1 and SEQ ID NO:2"

8. Claims 33 and 34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 33 and 34 are vague and indefinite because the phrase "stringent hybridization conditions" is vague and indefinite because hybridization conditions can vary considerably. A number of parameters govern the stringency of the hybridization including the hybridization temperature, hybridization time, washing temperature, washing time, formamide concentration, detergent concentration, and salt concentration. Changes in these parameters will affect the specificity of the binding. Thus, in order to ascertain the metes and bounds of the patent protection, the skilled artisan would require a knowledge of these specific parameters. The claim does not clearly and unambiguously set forth the appropriate reaction conditions. The rejection may be overcome by clearly setting forth in the claim the reaction conditions encompassed by a stringent hybridization, as supported by the disclosure, paragraph 096.

9. Claim 43 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 43 is drawn to a purified polynucleotide sequence originating from a gene of *M. tuberculosis* comprising a mutator allele.

It is unclear from the claim language if the claimed polynucleotide sequence actually comprises a mutator allele, or if the claimed polynucleotide sequence does not comprise a mutator allele but is from a whole gene comprising a mutator allele.

10. Claim 52 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 52 is drawn to a kit comprising  $\geq 1$  polynucleotide "probe" selected from the purified polynucleotide sequence claimed in any one of claim 48-51.

It is unclear what is the actual identity of the claimed "probe" due to the unclear language of claim 52. For example, is a probe the entire polynucleotide sequence of claim 48 or merely a portion of the polynucleotide?

Claim 43 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the specific mutator alleles disclosed by the specification, does not reasonably provide enablement for any/all other still to be discovered mutator alleles of *M. tuberculosis*. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction

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or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

The nature of the invention is a purified polynucleotide sequence originating from any gene of *M. tuberculosis* comprising a mutator allele.

The state of the prior art as evidenced by applicant's submitted documents indicates that while mutator alleles in *E. coli* and other bacteria are well-known, such mechanisms in *M. tuberculosis* are not readily homologous (Taddel et al, *Nature*, Vol 387, pp. 700-702, 1997; Tenaillon et al, *Genetics*, Vol. 152, pp. 485-493, 1999). Therefore, because of a lack of predictability in the art and only very specific guidance/examples provided in the specification, the scope of the claimed invention, i.e., purified polynucleotide sequences originating from any gene of *M. tuberculosis* comprising a mutator allele, constitutes merely an invitation to experiment without a reasonable expectation of success.

### **Claim Rejections - 35 USC § 102**

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 39 and 46 are rejected under 35 U.S.C. 102(b) as being anticipated by Du (Accession number AD000020, direct submission, GenBank, 10 December 1996).

Claim 39 is drawn to a polynucleotide delimited upstream by SEQ ID NO:1, downstream by SEQ ID NO:2, and comprising SEQ ID NO:29. The directly submitted sequence teaches a

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polynucleotide delimited upstream by SEQ ID NO:1 (residues 17919-17939), downstream by SEQ ID NO:2 (residues 18734-18718), and comprising SEQ ID NO:29 (residues 18115-18537).

Claim 46 is drawn to a polynucleotide comprising SEQ ID NO:29. Du teaches a polynucleotide comprising SEQ ID NO :29 (residues 18115-18537).

13. Claims 42, 46, and 47 are rejected under 35 U.S.C. 102(b) as being anticipated by Bourn et al (Accession number U65786, direct submission, GenBank, 1 August 1996).

Claim 42 is drawn to a polynucleotide delimited upstream by SEQ ID NO:7, downstream by SEQ ID NO:8, and comprising SEQ ID NO:28. The directly submitted sequence teaches a polynucleotide delimited upstream by SEQ ID NO:7 (residues 605-621), downstream by SEQ ID NO:8 (residues 1275-1259), and comprising SEQ ID NO:28 (residues 704-1198).

Claim 42 is drawn to a polynucleotide comprising SEQ ID NO:28. Bourn et al teaches a polynucleotide comprising SEQ ID NO :28 (residues 704-1198).

Claim 47 is drawn to a purified polynucleotide comprising SEQ ID NO:6, 7 or 8. Bourn et al teaches a polynucleotide comprising SEQ ID NO:6 (residues 779-795), SEQ ID NO :7 (residues 605-621) and SEQ ID NO:8 (residues 1275-1259).

14. Claim 46 is rejected under 35 U.S.C. 102(b) as being anticipated by Gicquel et al (WO99/09186).

Claim 46 is drawn to a polynucleotide comprising SEQ ID NO:32 Bourn et al teaches a polynucleotide comprising SEQ ID NO :32 (residues 1-2406 of SEQ ID NO:36D).

### **Conclusion**

15. Claims 26, 28, 29, 31, 33, 34, 39, 42, 43, 46, 47, and 52 are rejected. Claims 32, 35-38, 40, 41, 45, and 48-51 are allowed.




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16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's Supervisor, Jeffrey Siew, can be reached on (571)272-0787.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
RODNEY P. SWARTZ, PH.D.  
PRIMARY EXAMINER  
Art Unit 1645

November 22, 2006